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METHOD AND APPARATUS FOR PROVIDING MEDICAL TREATMENT THERAPY BASED ON CALCULATED DEMAND

DESCRIPTION

Technical Field

The present invention relates generally to a medical treatment apparatus for providing a medical treatment to a patient based on a calculated demand, and more specifically to a medical treatment administration system for delivering a medical treatment to a patient that is automatically triggered and controlled by a patient's physiological and/or environmental conditions.

Background of the Invention

For many types of medical treatments, the impact and ultimate usefulness of the treatment depends on the patient's tolerability and sensitivity to the treatment. Such measures assist physicians in accurately and effectively treating patients. To date, however, most medical treatments are provided to the patient based on objective measurements, rather than on actual measurements of the specific subject or environment of the subject.

For example, typical medical treatment parameters for many drug therapies are provided based on the generic circadian system. Under the circadian system it has been know in the medical industry that typical biological functions of plants and animals reoccur at approximately 24-hour intervals. In humans, the body's clock is located in the suprachiasmatic nucleus (SCN), a distinct group of cells found within the hypothalamus. The SCN controls or coordinates the circadian rhythm in the human body. Typically, a human's circadian rhythm is calibrated by the alternation of light through the eyes and darkness via melatonin secretion by the pineal gland.

Furthermore, the cellular metabolism and proliferation in normal human tissues display similar rhythms, and thus have predictable amplitudes and times of peak and trough. Such rhythms influence drug pharmacology, tolerability, and ultimate usefulness. For example, it has been thought that the circadian rhythm influences the uses and effects of anti-cancer medication, including tolerability and anti-tumor efficacy in cancer treatment. Therefore, in chronopharmacologic intervention, anti-cancer drugs are delivered according

to a standard circadian rhythm, especially with chemotherapy. For example, Floxuridine delivery is typically given in four doses, each dose dependent on the time of the day:

14% of dose between 9 am and 3 pm;
68% of dose between 3 pm and 9 pm;
14% of dose between 9 pm and 3 am; and,
4% of dose between 3 am and 9 am.

Generally, the time at which the medication is delivered is selected by the physician to objectively coincide with changes in the patient's metabolism. However, the circadian rhythm is merely an estimate of the changes in the patient's metabolism, and is not based on the actual patient's metabolism. Thus, whether the medication delivery actually coincides with the patient's actual metabolism is neither evaluated nor determined.

Additionally, different medical treatments have different optimum dosing time-profiles. For example, different anti-tumor drugs are typically dosed at different times: Epirubicin and Daunorubicin are typically dosed at 2 hours after light onset; Cyclophasphamide is typically dosed at 12 hours after light onset; Cisplatin is typically dosed at 15 hours after light onset; and, Vinblastine is typically dosed at 18 hours after light onset. As can be seen, different drugs have different mechanisms of action.

Other factors, however, may also affect proper medical treatment. For example, the minimum sensitivity of normal tissue is thought to be related to the enzyme levels that affect drug metabolism (e.g., glutathione). An overall driver of these variables is thought to be the rest-activity cycle of the patient. Because of this effect, it is known that laboratory rat studies should be conducted with the animal subjected to a 12 hour light, and 12 hour dark cycle.

Nevertheless, it is known that different patients, and with regard to cancer treatment, even different tumors, are not all on the same circadian cycle. Thus, there are at least two aspects one needs to optimize during circadian therapy: (1) the peak sensitivity of the tumor(s); and, (2) the minimum sensitivity of the normal tissues.

Standard chronopharmacologic intervention takes advantage of the circadian rhythm in drug tolerability by controlling the timing and dosing. Thus, it can reduce the effect of toxicity and improve the quality of life for the patient. Furthermore, with many drugs, including chemotherapy drugs, by administering a higher maximum tolerated dose at the least toxic circadian time, an improvement in survival may be derived. However, as explained above, there are numerous flaws with providing medical treatments following the standard circadian system.

Thus, a method and a means for subjectively determining, triggering and controlling the delivery of medical treatments for a specific patient is highly desirable.

Summary of the Invention

The method and apparatus for providing medical treatment therapy of the present invention is based on actual data to calculate a strategic control. Generally, the system of the present invention comprises a medical device, a control algorithm coupled to the medical device, and a sensing device.

According to one aspect of the present invention, the sensing device automatically receives a signal and transfers the signal to the control algorithm. The control algorithm processes the signal received from the sensing device to determine whether the medical treatment should be delivered to the patient. Based on the result of the processed signal, the control algorithm develops a feedback control to control the delivery of the medical treatment to the patient.

According to another aspect of the present invention, a medical apparatus is provided for delivering a treatment to a patient. The medical apparatus comprises a medical device having a medical treatment, and a controller electrically connected to the medical device. The controller has a control algorithm stored therein that dynamically processes a signal received from a sensing device. The control algorithm develops a feedback control based on a result of processing the signal to determine whether medication should be delivered from the medical device to the patient and provides the feedback control to the medical device to control the delivery of the medical treatment to the patient.

According to another aspect of the present invention, the sensor is coupled to a patient to receive information from the patient concerning the physiological condition of the patient. The information received from the sensor is transferred to the control algorithm, and the information is processed to control the delivery of the medication from the medical device to the patient.

According to another aspect of the present invention, the signal concerning the patient's physiological condition is selected from the group consisting of: the patient's heart rate, the patient's body temperature, the patient's activity, the patient's metabolic demand, the patient's cellular metabolism, and the patient's proliferation.

According to another aspect of the present invention, the sensor receives a signal from the patient's environment. The sensor transmits the signal to the processor, wherein

the processor regulates the distribution of medical treatment from the medical device to the patient over a period of time based on a calculation of the signal.

According to another aspect of the present invention, the medical treatment administration system for delivering a medical treatment to a patient comprises a medical device and a first sensor. The medical device has a processor that regulates the distribution of medical treatment to the patient over a period of time based on a signal from the sensor. The first sensor, which is coupled to the processor, receives a signal from the patient concerning the patient's physiological condition and transmits the signal to the processor. The processor then processes the received signal to regulate the distribution of medical treatment from the medical device.

According to another aspect of the present invention, the medical treatment administration system further comprises a second sensor coupled to the processor. The second sensor obtains a signal based on a condition of the patient's environment and transmits the signal to the processor. Depending on the specific medical treatment to be administered to the patient, the processor requests the signal from one of the first sensor and second sensor.

According to another aspect of the present invention, the processor requests signals from both of the first sensor and second sensor, and the processor processes the signals and regulates the distribution of medical treatment from the medical device based on the cumulative result of the processed signals.

According to another aspect of the present invention, the sensor receives a plurality of signals from the patient concerning the patient's physiological condition and transmits the signals to the processor. The processor receives the signals, processes the signals and regulates the distribution of medical treatment from the medical device based on the cumulative result of the processed signals.

According to another aspect of the present invention, the medical treatment administration system further comprises a second medical device that delivers a medical treatment to the patient. The processor receives a signal from the second sensor, processes the second signal, and regulates the distribution of medical treatment from the second medical device to the patient.

According to another aspect of the present invention, the medical apparatus, comprises a programmable medical device for administering a medical treatment to a patient, and a controller. The programmable medical device has a first input device for entering control commands for the programmable medical device, and the controller has a

second input device for entering control commands for the controller. The input devices may be located in the same location, or one or more input devices may be located at a remote location, which may or may not be the same remote location.

According to another aspect of the present invention, the sensing device of the present invention comprises a vital signs monitor coupled to the patient. The vital signs monitor obtains a first signal from the patient and transfers a second signal to the controller.

According to another aspect of the present invention, the sensing device comprises an activity sensor coupled to the patient. The activity sensor obtains a first signal from the patient and transfers a second signal to the controller.

According to another aspect of the present invention, the sensing device obtains a signal based on the cellular metabolism of the patient.

According to another aspect of the present invention, the sensing device obtains a signal based on the cellular proliferation in the patient.

According to another aspect of the present invention, the sensing device comprises a light sensor coupled to the controller, the light sensor obtaining a first signal based on the ambient light and sending a second signal to the controller.

According to another aspect of the present invention, the sensing device and the controller having the control algorithm are an integral component.

According to yet another aspect of the present invention, a method to provide medical treatment for a patient is provided. The delivery of the medical treatment may be triggered by one or more physiological or environmental conditions of the patient.

Other features and advantages of the invention will be apparent from the following specification taken in conjunction with the following drawings.

Brief Description of the Drawings

To understand the present invention, it will now be described by way of example, with reference to the accompanying drawings in which:

FIG. 1 is a block diagram of a medical treatment administration system of the present invention;

FIG. 2 is a block diagram of a variation of the medical treatment administration system of FIG. 1, including remote controlling;

FIG. 3 is a block diagram of another variation of the medical treatment administration system of FIG. 1, including where the controller is a component of the medical device;

FIG. 4 is a block diagram of another variation of the medical treatment administration system of FIG. 1, including a variety of sensing devices;

FIG. 5 is a block diagram of another variation of the medical treatment administration system of FIG. 1, including a variety of sensing devices;

FIG. 6 is a block diagram of another variation of the medical treatment administration system of FIG. 1, including where the controller and the sensing device are an integral component;

FIG. 7 is a block diagram of another variation of the medical treatment administration system of FIG. 1, including a plurality of medical treatment devices;

FIG. 8 is a block diagram of another variation of the medical treatment administration system of FIG. 7, including a processor for a plurality of medical treatment devices;

FIG. 9 is a front elevation view of one embodiment of an infusion pump utilized with the present invention; and,

FIG. 10 is a block diagram of one type of a control algorithm of the present invention.

Detailed Description of the Preferred Embodiment

While this invention is susceptible of embodiments in many different forms, there is shown in the drawings and will herein be described in detail preferred embodiments of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiment illustrated.

Referring now in detail to the Figures, there is shown a medical treatment administration system 10 utilizing a medical treatment delivery control to distribute the medical treatment based on the condition of the specific patient and/or a change in the environment of the specific patient. As shown in FIG. 1, one embodiment of the medical treatment administration system 10 includes a medical device 12, a control algorithm 26 coupled to the medical device 12, and a sensor 16 coupled to the patient 18. The medical device 12 may be one of a variety of devices, including, but not limited to infusion pumps, ventilators, insulin delivery devices, and anesthesia delivery devices, however, one of ordinary skill in the art would understand that other medical devices could be utilized without departing from the scope of the invention. Additionally, the medical device 12 may be programmable.

In one embodiment, an infusion pump 20, illustrated in FIG. 9, is utilized as the medical device 12 for administering a liquid medicant to the patient 18. Typically, the medical device 12 has a supply of medication (not shown) and a means for ~~delivering the~~ medication (not shown) to the patient 18. Mea With the infusion pump 20, the supply of medication is typically a liquid medicant retained in a syringe or IV-type bag. Additionally, with an infusion pump 20 the means for delivering the medication includes a liquid injection device, often a hollow needle or catheter, adapted to be connected to the patient, a conduit or tubing connected to the liquid injection device, a pumping mechanism for pumping the liquid medicant through the conduit and into the patient via the liquid injection device, and a controller for controlling the pumping mechanism. However, when other types of medical devices are utilized, the medical treatment and the means for delivering the treatment will likely vary to be in accord with the specific medical device. ? For example, a ventilator provides oxygen to the patient, an insulin delivery mechanism delivers insulin to the patient, and an anesthesia device provides anesthesia gas or anesthesia medication to the patient, each with the appropriate delivery means.

In the embodiment illustrated in FIG. 1, the sensor 16 is coupled to the patient 18 and receives information from the patient 18 concerning the physiological condition of the patient 18. As is understood by one of ordinary skill in the art, such physiological conditions may include, but are not limited to, the patient's heart rate, the patient's body temperature, the patient's blood pressure, the patient's activity level, the patient's cellular metabolism, the patient's cellular proliferation, the patient's metabolic demand, the patient's food intake, and the patient's SpO_2 level, etc. Such factors, as well as other factors known by one of ordinary skill in the art, are understood to be triggering events for the distribution of medical treatment, and especially drug therapy, to individuals in the treatment of medical conditions. Additionally, the sensing device may comprise an input device for receiving a manual input. The manual input may be provided by a health care provider or the patient. One example of the patient providing input for the sensing device is where the medical device 12 is a insulin delivery mechanism. As such, the patient may provide input to the sensor indicating the type of food consumed by the patient.

In one embodiment, multiple sensors 16 are comprised in a portable multiparametric physiological monitor (not shown) for continuous monitoring of certain physical parameters of the patient. The monitor has sensors 16 including: EKG electrodes, a chest expansion sensor, an accelerometer, a chest microphone, a barometric pressure sensor, a body

temperature sensor and an ambient temperature sensor. Each of the sensors provides an output signal to an analog-to-digital converter (ADC).

In such an embodiment, the sensors 16 may be provided in a body strap (not shown) which, could comprise a chest strap upon which are distributed the various sensors and supporting electronics. (It will be recognized by those skilled in the art that a multiparametric monitoring device may also be mounted by a strap about a part of the body other than the chest). The chest strap is adapted to fit around the torso of the patient 18.

The variety of parametric sensors 16 are located on the strap as most appropriate for the parameter (or parameters) which it detects. Each of the sensors 16 provides an electrical input to analog circuitry which filters and amplifies the sensor signals, as known in the art of signal processing, and outputs them to an analog-to-digital converter, which may be part of controller hardware. The sensors in the strap may be as follows: a pectoralis temperature sensor which senses the temperature of the surface of the patient's chest; barometric pressure sensor which senses the ambient barometric pressure of the patient's environment; chest expansion (ventilation) sensor which detects the tension on the chest strap as an indication of the expansion and contraction of the patient's chest; accelerometer which detects movement and inclination of the patient's body; ambient temperature sensor which senses the ambient temperature of the patient's environment; microphone which detects sounds from within the patient's torso; underarm temperature sensor which senses the temperature of the side of the patient's torso underneath the arm; and, EKG electrodes which detect electrical signals caused by action of the heart muscle. The EKG electrodes are used in combination with ground, or reference, electrodes, and are placed in contact with the skin of the patient's chest to detect electrical signals generated by the pumping action of the patient's heart muscle. The EKG (electrocardiogram) is an indication of the patient's heart activity, as is well known in the a field of medicine.

Also as shown in FIG. 1, sensor 17 may be provided in addition to, or in substitution of, sensor 16. Sensor 17 obtains information concerning the environment of the patient 18. Typically, the sensors 16,17 automatically obtain the signal concerning the physiological condition of the patient and/or the condition of the environment, respectively, without intervention from the patient 18. Depending on the information required by the control algorithm 26, multiple sensors 16,17 may be utilized in series or in parallel (FIGS. 1, 4, 7 and 8).

The sensors 16,17 may be any device that is capable of receiving a signal (i.e., information), whether from an individual 16, such as a signal concerning the individuals

heart rate, body temperature, blood pressure, activity level, cellular metabolism, cellular proliferation, metabolic demand, SpO_2 level, etc., or based on an environmental condition 17, such as the ambient temperature, ambient light condition, etc. As shown in FIGS. 4 and 5, such sensors 16,17 may include, but are not limited to, vital signs monitors, blood pressure monitors, light sensors, environmental sensors and activity sensors. Additionally, as shown in FIG. 6, rather than being a separate component, the sensors 16,17 may be integral with the controller 28.

The signal received from the sensor 16,17 is electrically transferred 24 to a control algorithm 26. As shown in FIGS. 2, 3 and 6, the control algorithm 26 may be a part of the controller 28 (also referred to as a processor). Additionally, as shown in FIG. 3, the controller 28 may be a component of the medical device 12. Depending on the specific medical treatment to be administered to the patient 18, the control algorithm 26 may request signals from one or more sensors 16,17. While it is understood that the rest-activity or metabolism cycle of a patient can be determined invasively by measuring various elements including blood cell counts, plasma or serum concentration of cortisol, liver enzymes, and creatine, other methods may also be available. For example, the rest-activity or metabolism cycle of a patient can also be measured non-invasively by the vital sign or activity of the patient. Additionally, it has been found that the body temperature of a patient drops during the night, and that a patient's heart rate drops when the patient is at rest. Accordingly, such signals are obtained by the sensors 16,17, and such information is transferred 24 to the control algorithm 26 for processing.

It is understood that the control algorithm 26 will likely be different for each different medical treatment, and further it is also understood that the control algorithm 26 may be different for different patients, even for the same medical treatment. One example of a control algorithm 26 is shown in FIG. 10. As shown in FIG. 10, the control algorithm 26 is utilized to control the delivery of medication to a patient as a function of the patient's 18 heart rate. In this embodiment, the control algorithm 26 receives a signal of the patient's heart rate from one of the sensors 16. The control algorithm 26 processes the signal 30 by comparing the signal with the maximum heart rate. If the heart rate signal is less than the maximum heart rate signal the control algorithm develops a feed back control 32 to reduce the rate of infusion of the infusion pump 12 by 2%. If the heart rate signal is not less than the maximum heart rate signal the control algorithm further determines if the infusion therapy has been completed. If the infusion therapy has not been completed, feedback control 32 is provided to continue infusion. Additional processing 30 of the heart rate signal

is subsequently continued. If the infusion therapy has been completed, feedback control 32 is provided to stop the infusion pump 12.

After the control algorithm 26 receives the transferred signal 24 it processes 30 the signal through the control algorithm 26 and the resultant feedback control 32 is developed. If multiple signals are requested and received from a plurality of sensors 16,17, each required signal is processed 30 through the control algorithm 26 as programmed, and a resultant feedback control 32 is developed. The feedback control 32 operates as a control signal for the medical device 12 to control or regulate delivery of the medical treatment to the patient 18.

This is accomplished by transferring 34 the feedback control 32 that was developed by the control algorithm 26 to the medical device 12. The feedback control 32 provides the commands for operation of the medical device 12. The feedback control 32 typically provides one of two signals or commands to the medical device 12: deliver 36 medical treatment to the patient 18 or do not deliver 38 medical treatment to the patient. If the feedback control 32 provides a signal to deliver 36 the medical treatment it may also provide a signal to the medical device 12 indicating the amount and rate of treatment to provide to the patient 18. Such a signal may include increasing or decreasing the rate of medication delivery.

As shown in FIG. 7, multiple medical devices 12a, 12b may be utilized to deliver 36 medical treatments to the patient 18. The specific medical treatments may be the same, and may merely be dosed differently, or each medical device 12a,12b may deliver 36 a different medical treatment to the patient 18. Further, as also shown in FIG. 7, separate control algorithms 26a,26b may be utilized for each medical device 12a,12b, respectively. The embodiment of FIG. 7, utilizes two distinct control algorithms 26a,26b, and numerous sensors 16a, 16b and 17. Sensors 16a, 17 transfer 24 signals to control algorithm 26a, which, depending on the treatment to be delivered 36 to the patient 18, may process 30 the signals from one or both of the sensors 16a,17 to develop a resultant feedback control 32a. Sensor 16b transfers 24 a signal to control algorithm 26b which likewise processes 30 the signal and develops a resultant feedback control 32b. Feedback control 32a is sent to the first medical device 12a to control the delivery 36a of medical treatment to the patient 18, while feedback control 32b is sent to the second medical device 12b to control the delivery 36b of medical treatment to the same patient 18.

Conversely, as shown in FIG. 8, one control algorithm 26 may control multiple medical devices 12a,12b. In this embodiment, one control algorithm 26 is utilized with a

plurality of sensors 16a, 16b and 17. Sensors 16a, 16b and 17 transfer 24 signals to the control algorithm 26, which, depending on the treatment to be delivered 36 to the patient 18, may process 30 the signals from one or more of the sensors 16a, 16b and 17 to develop one or more resultant feedback controls 32a,32b. Feedback control 32a is sent to the first medical device 12a to control the delivery 36a of medical treatment to the patient 18, while feedback control 32b is sent to the second medical device 12b to control the delivery 36b of medical treatment to the same patient 18. Accordingly, in this embodiment the control algorithm 26 for the first medical device 12a is the same control algorithm 26 as for the second medical device 12b.

Because the medical treatment apparatus 10 may be utilized with different treatment therapies, the control algorithm 26 is generally modified or changed for each different treatment therapy. Thus, as shown in FIGS. 1 and 2, an input device 42 is generally provided to adjust and set the control parameters 44 of the control algorithm 26. The input device 42 may be coupled to the controller 28 or directly to the control algorithm 26. While the control algorithm 26 may be manually input, it may also be dynamically downloaded as from a database or network.

Further, as shown in FIG. 1, the medical device 12 may also have an input device 48 therefor. The input device 48 for the medical device 12 allows a user, typically an authorized clinician to enter control commands 50 to adjust or set control parameters for the medical device 12. In an alternate embodiment, the input device for the medical device 12 is the same as the input device for the controller/control algorithm.

As shown in FIG. 2, a remote controller 46 (i.e., a remote input device) may be provided for remotely adjusting or setting the control parameters of the control algorithm 26 and/or controller 28. U.S. Patent No. 5,885,245, assigned to the assignee of the present invention, discloses a remote controller, among other things, and is expressly incorporated herein by reference, and made a part hereof. The remote controller 46 is disposed at a room location (i.e. a second location) remote from the room location at which the medical device 12 is located (i.e., a first location). The remote controller 46 could be disposed in a different room of the same building in which the medical device 12 is disposed, or in a different building than the one in which the medical device 12 is disposed. The remote controller 46 is connected to a conventional voice/data modem 52 via a data link 54, and the modem 52 is also connected to a telephone 56 via a voice link 58. The medical device 12 is connected to a conventional voice/data modem 60 via a data link 62, and the modem 60 is connected to a telephone 64 via a voice link 66. The two modems 52, 60 are interconnected to bidirectional

voice and data communication via a communication link 68, which could be a telephone line, for example. Additionally, the remote controller 46 may communicate with the control algorithm 26 via an internet, an intranet and a wireless network. Furthermore, the remote controller 26 may be a server.

While the specific embodiments have been illustrated and described, numerous modifications come to mind without significantly departing from the spirit of the invention, and the scope of protection is only limited by the scope of the accompanying Claims.